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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,680	05/24/2001	Brian J. Staskawicz	42250/234021 (5830-4A)	2026

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/864,680

Applicant(s)  
Staskawicz et al

Examiner  
Medina Ibrahim

Art Unit  
1638



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 23, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 3 is/are allowed.
- 6) ☒ Claim(s) 2 and 4 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

Applicant's response filed 12/23/02 in reply to the Office action mailed 09/25/02 and amendment A have been entered. New claims 4 and 5 are added. Therefore, claims 1-5 are pending and are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not set forth below have been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

Claim 2 remains rejected and new claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated protein comprising the amino acid sequence set forth of SEQ ID NO:3, does not reasonably provide enablement for an isolated protein comprising an amino acid sequence having at least 85% and 90% sequence identity to the amino acid sequence of SEQ ID NO:3 and having Bs2 biological activity. This rejection is repeated for the same reason as set forth in the last Office action. Applicant's arguments filed 12/23/02 have been fully considered but are not deemed persuasive.

Applicant argues that the instant specification provides sufficient guidance for how to make and use the claimed protein having amino acid sequence identity of 85% and 90% to SEQ ID NO:3. Applicant relies upon the following points to support his position: 1) the proteins vary from SEQ ID NO:3 by structural parameters, and that guidance for determining said structural parameters are disclosed in the instant

specification 2) the proteins encompass functional variants and fragments comprising amino acid substitutions, deletions, truncations, and insertions, and that guidance for amino acid alterations without altering BS2 protein biological activity are provided in the specification. 3) methods for testing a protein having BS2 protein biological activity are also disclosed in the specification. Therefore, one skilled in the art who wishes to practice the invention will need two steps: a) to generate proteins having amino acid sequence identity of at least 85% and 90% to SEQ ID NO:3; and b) to assay the proteins for BS2 biological activity. Applicant finally asserts that no undue experimentation is required to practice the claimed invention. Applicant urges that the rejection be withdrawn.

The Examiner maintains that the scope of the claims is broader than the enabling disclosure for the same reasons disclosed in the last Office action. In addition, the specification merely provides guidance regarding alteration of a single amino acid in a given protein to produce variants. However, no specific guidance has been provided as where and how SEQ ID NO:3 can be modified so that the resultant variants will retain BS2 protein biological activity. In the specification, pages 17 and 18, Applicant states that Bs2 variants can be produced by modifications that involve conservative substitution of amino acids which are unlikely to change the BS2 protein biological activity, while substitutions that are less conservative are likely to effect protein function. However, according to Lazar et al disclosed in page 4 of the last Office action, conserved substitutions may not result in predictable results. Lazar showed that

the conservative substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor-alpha while non-conservative substitutions with alanine or asparagine had no effect. In addition, neither Applicant's response nor the state of the art provides evidence that structural identity between two proteins inherently implies that the two proteins share similar biological activity. Therefore, it is unpredictable whether substitutions of amino acids that are conserved in BS2 would result in functional variants, absent further guidance.

Regarding Applicant's arguments against undue experimentation, it is note that while determination of sequence identity, and assays for testing proteins having antipathogenic activity are well within the level of one skilled in the art and clearly would not require undue experimentation, making and testing protein sequences that meet both the structural and the functional limitations as recited in the claims are not considered to be routine. These tests are considered undue experimentations, given the state of the art, the unpredictable nature in protein modifications, the limited guidance and the limited working examples in the specification, as stated in the last Office action.

Therefore, one skilled in the art would not be able to make proteins having at least 85% and 90% sequence identity to SEQ ID NO:3 and BS2 protein biological activity, without undue trial and error experimentations. The rejection is maintained

***Written Description***

Claim 2 remains rejected and new claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the same reasons of record as set forth in the last Office action. Applicant's arguments filed 12/23/02 have been fully considered but are not deemed persuasive.

Applicant argues that the claimed isolated proteins are adequately described because the recited structural characteristics, namely, having at least 85% and 90% sequence identity to SEQ ID NO:3 and the functional characteristics of BS2 protein biological activity are sufficient to satisfy written description requirement. Applicant refers to Example 14 to support his position.

However, while structural characteristics of 85% and 90% sequence identity to SEQ ID NO:3 is a predictable structure, Applicant has not provided evidence that proteins with said structural characteristics are predictable to have BS2 biological function. In other words, there is no known correlation between the structure of a BS2 protein and its function.

Regarding the reference to Example 14 of Revised Interim Written Description Guidelines, the two situations are not analogous because the rejected claims are drawn to variants with 85% and 90% sequence identity to SEQ ID NO:3. Therefore, the Example 14 does not appear to support Applicants' position.

The rejection is maintained.

***Remarks***

Claims 1-5 are free of the prior art of record.

Claims 1 and 3 are allowed.

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using

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Art Unit: 1638

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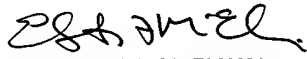
fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 8:30 AM to 5:30 PM and every other Friday from 9:00AM to 5:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

April 3, 2003  
mai

  
**ELIZABETH F. McELWAIN**  
**PRIMARY EXAMINER**  
**GROUP 1800**